657—13.6 (126,155A) Policies and procedures. A written policy and procedure manual shall be prepared, implemented, maintained, and adhered to for the compounding, dispensing, delivery, administration, storage, and use of sterile preparations. The manual shall establish policies and procedures relating to subjects identified in this and other rules within this chapter.

13.6(1) *Quality assurance program.* The policy and procedure manual shall include a quality assurance program pursuant to rule 657—13.31(155A).

13.6(2) *Sampling.* The policy and procedure manual shall include procedures that require sampling of a preparation as provided in rule 657—13.29(126,155A) or if microbial contamination is suspected.

13.6(3) *Preparation recall.* The policy and procedure manual shall include procedures for the recall of dispensed preparations that fail to meet product quality standards.

13.6(4) *Hazardous products and infectious waste.* The policy and procedure manual shall include procedures for proper handling of hazardous drug products and infectious waste, if applicable.

13.6(5) *Periodic review.* The policy and procedure manual shall be periodically reviewed. Policies shall specify the frequency of review. The manual shall be available for inspection and copying by the board or agents of the board.

[**ARC 0596C**, IAB 2/6/13, effective 3/13/13]